DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 22, 2016

Olympus Medical Systems Corp.
% Sheri Musgnung
Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway, Po Box 610
Center Valley, PA 18034-0610

Re: K160098
Trade/Device Name: Single Use Aspiration Needle NA-U401SX
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: FCG
Dated: January 15, 2016
Received: January 19, 2016

Dear Sheri Musgnung,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160098

Device Name
Single Use Aspiration Needle NA-U401SX

Indications for Use *(Describe)*
This instrument has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
Single Use Aspiration Needle NA-U401SX

January 15, 2016

5.1 General Information

■ Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan Establishment Registration No: 8010047
■ Official Correspondent:	Sheri L. Musgnung Manager, Regulatory Affairs Olympus Corporation of the Americas 3500 Corporate Parkway PO Box 610 Center Valley, PA 18034-0610, USA Phone: 484-896-3147 FAX: 484-896-7128 Email: sheri.musgnung@olympus.com
■ Manufacturer:	Aomori Olympus Co., Ltd. 2-248-1 Okkonoki, Kuroishi-shi, Aomori, 036-0357, Japan Establishment Registration No.: 9614691

5.2 Device Identification

■ Device Trade Name:	Single Use Aspiration Needle NA-U401SX
■ Common Name:	Aspiration Needle
■ Regulation Number:	876.1075
■ Regulation Name:	Gastroenterology-urology biopsy instrument
■ Regulatory Class:	II
■ Classification Panel:	Gastroenterology and urology
■ Product Code:	FCG

5.3 Predicate Device Information

■ Device Name:	Single Use Aspiration Needle NA-201SX-4022
■ Common Name:	Aspiration Needle
■ Applicant	Olympus Medical Systems Corp.
■ 510(k) No.	K050503

5.4 Device Description

The single use aspiration needle NA-U401SX (aka ViziShot 2) is intended to be used in conjunction with Olympus ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA). It consists of a handle section and insertion section. The handle section is connected to the endoscope's instrument channel port via the single use adapter biopsy valve (MAJ-1414). The insertion section is composed of the sheath, needle, and stylet. The needle is stored in the sheath and extended from the sheath to puncture the target tissue to collect specimen by moving the needle slider on the handle. A syringe is attached to the aspiration port on the handle section to aspirate the specimen that was punctured with the needle. The needle is dimpled for echo enhancement and also consists of an oval portion for better angulation.

The subject device will be sold with or without medallion syringe manufactured by Merit Medical, which consists of VACLOK Syringe and Stopcock.

5.5 Indications for Use

This instrument has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract.

5.6 Comparison of Technological Characteristics

Compared to the predicate device, the proposed subject device; Single Use Aspiration Needle NA-U401SX, has similar technological characteristics except for the following differences.

- Needle tube shape on proximal side
- Sheath composition
- Materials

The needle tube of the subject device has a part of oval portion on its proximal side whereas the predicate device consisted of a round shape. The sheath design is similar to another 510(k) cleared device, Olympus Aspiration Biopsy Needle (#K904667). The subject device utilizes new patient contact materials compared to PD.
Validation testing demonstrated that these technological features do not affect the safety or effectiveness of the subject devices.

5.7 Summary of non-clinical testing

·Performance testing was conducted on the following items to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.

- inserting into endoscope
- Flexibility of the insertion portion
- Piercing
- Ultrasound visibility
- Needle extraction and retraction
- Aspiration
- Withdrawal from endoscope
- Locking force of handle portion
- Limitation of needle depth

·Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

·Biocompatibility testing is performed in accordance with the FDA Guidance," Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, Blue Book Memo, G95-1".

The following standards have been applied to the Single Use Aspiration Needle NA-U401SX.

·ISO 10993-1
·ISO 10993-5
·ISO 10993-10
·ISO 10993-11
·ISO 11135
·ISO 14971
·ASTM F-1980-07

5.8 Conclusion

When compared to the predicate device, the Single Use Aspiration Needle NA-U401SX

does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.